

**K040904 PHILIPS HEARTSTART HOME DEFIBRILLATOR,
MODEL M5068A**Sep 16, 2004
162 days to decisionK040904 · Product code: **NSA** · Cardiovascular
Source: <https://www.510kdatabase.net/k040904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Automated External Defibrillator (NSA)
Date received	Apr 7, 2004
Decision date	Sep 16, 2004
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems
Location	Seattle, WA, US
Contact	TERESA SKARR
510(k) history	107 submissions · 105 cleared · 2002-2021

Philips Medical Systems is a Dutch multinational health technology company headquartered in Amsterdam with U.S. operations based in Seattle. The company evolved from a consumer electronics conglomerate founded in 1891 to a healthcare-focused organization. Philips Medical Systems has received FDA 510(k) clearances from total submissions between 2002 and 2021. The company's regulatory focus centered on Cardiovascular devices, which represented 79% of all submissions. This historical record reflects the company's significant presence in diagnostic ultrasound systems and pati...

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